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| 10/578,130 | 05/02/2006 | Alexander Von Weymarn-Scharli | A013-5786 (PCT) | 4982 |

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10/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/578,130 | Applicant(s) VON WEYMARN-SCHARLI, ALEXANDER | |
| | Examiner BENEDICT L.C. HANRAHAN | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-29 is/are pending in the application.
 4a) Of the above claim(s) 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 10-21 in the reply filed on 10/22/2009 is acknowledged. The traversal is on the ground(s) that the claims have been amended and are no longer restrictable. This is not found persuasive as the restriction was made FINAL in the previous office action.

2. Restriction was required under 35 U.S.C. 121 and 372. Even after amendment the claims are restrictable for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 10-21, drawn to a device for at least partial introduction a body passage.

Group II, claim(s) 22-29, drawn to a device for insertion into a body passage.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where the group of inventions is claimed in one and the same international application, the requirement for unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions considered as a whole, makes over the prior art. The inventions listed as Groups I, II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, although they share the same special technical feature, an inner and outer envelope body, this special technical feature does not define a contribution over the prior art for the following reasons: Claims 22-29 of Group II are either anticipated or obvious over EP 0371486. Therefore, the restriction is appropriate.

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2. Claims 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 10/22/2009.

3. Applicant is reminded that the restriction is made FINAL.

Claims Status

3. Claims 1-9 are canceled, claims 10-21 are examined on the merits and claims 22-29 are withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wayne et al. (US 6,203,525; hereinafter Wayne) in view of Bai (US 4,619,643).

6. Regarding claims 10 and 11, Wayne discloses a device 10 (Fig 1) for at least partial introduction into a body passage, the device comprising: a long, outer envelope body 36 (Figs. 1, 8A and 8B); a long inner body 12 and 28 (Figs. 1, 8A and 8B) that is at least partially peripherally surrounded by the envelope body 36 (Figs. 1, 8A and 8B); and a control device 20 (Figs. 1, 8A and 8B) that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner (Col 10, lines 11-29); wherein the control device 20 (Figs. 1, 8A and 8B) is itself formed by the arrangement and embodiment of the envelope body 36 (Figs. 1, 8A and 8B)

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and the inner body 12 and 28 (Figs. 1, 8A and 8B) and comprises no additional mechanical means in an annular intermediate region (Fig 8B, space between outer body 36 and the inner body 28) between the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B); the material of the envelope body and the inner body is flexible yet torsionally resistant (Col 1, lines 46-49 and 55-60) and the envelope body and the inner body can be rotated relative to one another by the control device in such a way that the corners of the inner body make contact at least partially with an inner wall of the envelope body (The shape of the inner and outer bodies impedes the coaxial rotational of the bodies relative to each other; Col 10, lines 11-29).

Wayne discloses that the geometry of the inner and outer body may be changed in order to prevent rotation (Col 10, lines 11-29) thus providing motivation and suggestion for different shapes, and an outer body with a hexagonal shape 36 (Fig 8B) but does not specifically disclose that the envelope body and the inner body have similarly-shaped polygonal cross sections. However, Bai discloses a double lumen catheter that is in the same field of endeavor as Wayne's catheter and is easy to insert and withdraw and prevents blood clotting and buckling (Col 1, lines 26-32 and 55-62 and Col 3, lines 8-19) where the inner and outer bodies have a polygonal cross section and the corners are lined up as shown in Figures 3c - 3e. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a polygonal cross section, as suggested and taught by Bai, for the purpose of making the outer body as small possible while still imparting structural rigidity so as to make insertion easy but prevent the chance of buckling. Wayne and Bai do not specifically disclose a hexagonal cross section on the inner and outer body. The combination of

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Whayne and Bai disclose a cross section with three sides on both bodies and a hexagonal shape on the outer body but do not disclose six sides on both the inner and outer body. It would be obvious to one skilled in the art at the time of the invention that six sides may have been used instead of three to impart structural rigidity, ease insertion of the device, and allow the shape of the outer configuration to adapt to different geometries within a body region as Whayne has disclosed using similar geometries on the inner and outer body (Whayne, Col 1, lines 46-49 and Col 10, lines 11-29). A change in form or shape is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955)

7. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 6,203,525; hereinafter Whayne) in view of Bai (US 4,619,643) and in further view of Avellanet et al. (US 5,542,938; hereinafter Avellanet).

8. Regarding claims 12 and 14, Whayne discloses a control device 20 (Figs. 1, 8A and 8B) but does not specifically disclose the introduction of a pressure medium to the annular intermediate region between the envelope body and the inner body. However, Avellanet discloses a magnetic guidewire coupling for catheter exchange that has a balloon expanded by filling it with a liquid. The balloon is used to change the contour and geometry in the cardiovascular system (Col 1, lines 21-25 and 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include liquid to be filled in a balloon, as suggested and taught by Avellanet, for the purpose of being able to contour the cardiovascular system in order to create lesions with the desired geometry and characteristics.

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9. Regarding claims 13 and 15, Wayne discloses an envelope body 36 (Figs. 1, 8A and 8B) and an inner body 12 and 28 (Figs. 1, 8A and 8B) and the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) but does not specifically disclose that the envelope body has a magnetic coating. However, Avellanet discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Col 3, lines 44-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellanet, Col 1, lines 46-49).

10. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wayne et al. (US 6,203,525; hereinafter Wayne) in view of Avellanet et al. (US 5,542,938; hereinafter Avellanet).

11. Regarding claim 16-17 and 20-21, Wayne discloses a device 10 (Fig 1) for at least partial introduction into a body passage, the device comprising: a long, outer envelope body 36 (Figs. 1, 8A and 8B); a long inner body 12 and 28 (Figs. 1, 8A and 8B) that is at least partially peripherally surrounded by the envelope body 36 (Figs. 1, 8A and 8B); and a control device 20 (Figs. 1, 8A and 8B) that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner (Col 10, lines 11-29); wherein the control device 20 (Figs. 1, 8A and 8B) is itself formed by the arrangement and embodiment of the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B) and comprises no additional mechanical

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means in an annular intermediate region (Fig 8B, space between outer body 36 and the inner body 28) between the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B). Wayne discloses the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) and the application of an electrical voltage (Col 5, lines 53-59).

Wayne does not disclose that the control device and the envelope body and the inner body are embodied in such a way that magnetic fields of different polarity can be alternately generated along the length of the envelope body and along the length of the inner body for the selective production of a mutual attraction of the two bodies. However, Avellanet discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Col 3, lines 44-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellanet, Col 1, lines 46-49).

12. Regarding claim 18, Wayne discloses a control device 20 (Figs. 1, 8A and 8B) but does not specifically disclose the introduction of a pressure medium to the annular intermediate region between the envelope body and the inner body. However, Avellanet discloses a magnetic guidewire coupling for catheter exchange that has a balloon expanded by filling it with a liquid. The balloon is used to change the contour and geometry in the cardiovascular system (Col 1, lines 21-25 and 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include liquid to be

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filled in a balloon, as suggested and taught by Avellanet, for the purpose of being able to contour the cardiovascular system in order to create lesions with the desired geometry and characteristics.

13. Regarding claim 19, Whayne discloses an envelope body 36 (Figs. 1, 8A and 8B) and an inner body 12 and 28 (Figs. 1, 8A and 8B) and the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) but does not specifically disclose that the envelope body has a magnetic coating. However, Avellanet discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Col 3, lines 44-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellanet, Col 1, lines 46-49).

Response to Arguments

14. Applicant's arguments filed 5/14/2010 have been fully considered but they are not persuasive. Applicant argues the restriction from the previous office action. Examiner disagrees with Applicant's arguments because the restriction was made final in the previous office action. Applicant argues that the inner body of Whayne is not a polygon. Examiner has not relied upon this position in the office action but will address this argument regardless. The inner body may be considered a dihedron which has a curved cross section and is a polygon. A circle is considered to be a polygon and is called a monogon or henagon. Applicant argues that the polygonal shapes of Bai would not allow for rotation. Examiner points Applicant's attention to

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Column 6, lines 62-64 which state that the inner body diameter may be varied. By varying the inner diameter, the inner body's rotation capability is also varied.

15. Applicant argues that Avellanet does not disclose that magnetic fields of different polarity can be alternately generated along the length of the envelope body and along the length of the inner body for the selective production of a mutual attraction of the two bodies. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. MPEP § 2114. Avellanet is capable of having alternate fields of magnetic polarity as it discloses alternately magnetized portions separated by ferromagnetic portions (Col 3, line 66 to Col 4, line 3 and Col 4, lines 37-40).

16. Applicant argues that Examiner has asserted that functional limitations are not accorded patentable weight. Examiner disagrees as all functional language has been considered. Please also see MPEP § 2114.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENEDICT L.C. HANRAHAN whose telephone number is (571)270-7854. The examiner can normally be reached on Monday-Friday, 8AM-5PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L. H./
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit
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